



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 56

[Docket No. FDA-2015-N-5052]

Administrative Actions for Noncompliance; Lesser Administrative Actions; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of August 17, 2016, for the direct final rule that appeared in the Federal Register of April 4, 2016. The direct final rule amends the regulations describing lesser administrative actions that may be imposed on an Institutional Review Board (IRB) that has failed to comply with applicable regulations. We are taking this action to ensure clarity and improve the accuracy of the regulations. This document confirms the effective date of the direct final rule.

DATES: Effective date of final rule published in the Federal Register of April 4, 2016 (81 FR 19033), confirmed: August 17, 2016.

FOR FURTHER INFORMATION CONTACT: Sheila Brown, Office of Good Clinical Practice, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993-0002, 301-796-6563.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 4, 2016 (81 FR 19033), FDA solicited comments concerning the direct final rule for a 75-day period ending June 20, 2016. FDA stated that the effective date of the direct final rule would be on August 17, 2016, no

later than 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 351, 352, 353, 355, 360, 360c-360f, 360h, 360i, 360j, 360hh-360ss, 371, 379e, 381; 42 U.S.C. 216, 241, 262.

Accordingly, the amendment issued thereby is effective.

Dated: July 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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